DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 9, 2015

Bistos Co., Ltd
% Young Chi
President
Bio-Med USA Inc.
27 New England Drive
Ramsey, New Jersey 07446

Re: K142799
Trade/Device Name: Model BT-220L and BT-220C
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: Class II
Product Code: HGM
Dated: June 2, 2015
Received: June 9, 2015

Dear Young Chi,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142799

Device Name
Ultrasonic Fetal Doppler
Model BT-220L and BT-220C

Indications for Use *(Describe)*
BT-220L/220C is a pocket sized ultrasonic fetal monitor that measures heart rate, which is displayed on an LCD display, and outputs fetal heart sounds through a built in speaker.
The fetal heart rate is measured using Doppler ultrasound.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

As required by CFR 807.92(c)

1. Manufacturer

Prepared July 1, 2015

Bistos Co., Ltd. Reg Nr:3006179052
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302 Galmachi ro, JungWon gu, Seoung Nam, GyungGi do, Rep of Korea
Tel: 82 2 2108 4626 Fax : 82 2 2108 4629

2. Submitter, Contact person

Mr. Young Chi / President
BioMed USA Inc.
27 New England Drive,
Ramsey, NJ 07505. U.S.A.
Tel: 973 278 5222 Fax: 201 934 6030
E mail: biomedusa@msn.com

3. Name of Device

Trade name	:	Model BT-220L and BT-220C
Common or usual name	:	Ultrasonic Fetal Doppler
Regulation number	:	884.2660
Regulation class	:	II
Product code	:	HGM
Classification panel	:	Obstetrics / Gynecology

4. Substantial Equivalence.

Bistos BT-220 Ultrasonic Fetal monitor is substantially equivalent in Intended use, Design, Function, Performance and all used material, direction to use, software, producing process, technology/principle of operation to already cleared BT-200T under 510(K)100885.

5. Indication for use.

The 220L/220C is a pocket sized ultrasonic fetal monitor that measures heart rate, which is displayed on an LCD display, and outputs fetal heart sounds through a built in speaker. the fetal heart rate is measured using Doppler Ultrasound.

6. Device Description

Bistos' BT-220L, BT-220C is a pocket size Fetal Doppler that measures the fetal heart rate and out put the fetal sound through built-in speaker.
By measuring fetal heart rate (FHR), they are able to predict fetal well-being.
BT-220 irradiates ultrasound wave to the abdomen of a pregnant women to detect.
The Doppler frequency signal and analyze, displays the heart rate in LCD screen.
The device also provides the heart sound from the heart of fetus.

Operating mode

- Continuous Pulsed Doppler
- Fetal Movement

Detail, Engineering design. Performing features, Operating mode, attached

7. Biocompatibility test.

All used material of patient contacted part was done Biocompatibility test by NAMSA (North American Science) by FDA guidance Blue Book Memo G95-1 use of ISO 10993 Biological Evaluation of Medical Device part 4, 5, 10.

Body contacting classification: Surface device, skin, limited less than 24 hrs.
The Skin contacting materials were found to be biocompatible.
Attached the Biocompatibility Certificate. (F)

8. Voluntary performed safety test result attached (B-E)

* HR Accuracy Measuring Report (G)
* Acoustic Output Test Report (F)
* CB Test Certificate (B, E)

9.Conclusion

Bistos' BT-220L/C Pocket size Fetal monitor in this submission is substantially equivalent to the already cleared BT-200T under K100885 at design, specification, intended use, used material, direction to use, software, Technology/principal operating and Performing etc in every angles.

The difference between the devices does not raise any new issues in safety or effectiveness

End of summary